



Memorandum

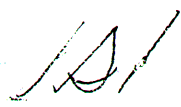
Date October 29, 1999
From Gloria J. Dunnavan, Director, Division of Compliance
Subject Y2K Information
To Veterinary Pharmaceutic and Feed Industry

We have provided the following information along with your drug listing verification package in our efforts to assist the pharmaceutical industry in preparation for Y2K issues.

INFORMATION FROM THE FOOD AND DRUG ADMINISTRATION'S
CENTER FOR VETERINARY MEDICINE – FDA HELPS INDUSTRY PREPARE FOR Y2K
Y2K COMPATIBILITY – A FEED INDUSTRY CHECKLIST

Y2K COMPATIBILITY – A CHECKLIST

Our intention is only to provide this education material to help you prepare for any Y2K issues. You do not have to return any of this information to the Center for Veterinary Medicine. This information is provided for your internal use only. Please contact me if you have any questions or comments concerning this information or issues related to Y2K problems.


Gloria J. Dunnavan, Director
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INFORMATION FROM THE FOOD AND DRUG ADMINISTRATION'S CENTER FOR VETERINARY MEDICINE

The following information is provided by the
Communications Staff, Center for Veterinary Medicine.

FDA HELPS INDUSTRY PREPARE FOR Y2K

As the millennium approaches, there is growing concern regarding the impact of Y2K (year 2000) issues on the identity, strength, quality, purity, and potency, as well as safety, efficacy, and availability of products regulated by FDA.

The animal health and feed industries are not exempt from computer problems at the beginning of the year 2000. Since virtually every organization's systems are composed of various layers of hardware and software that can be compromised by the Y2K problem, all businesses are vulnerable to potential Y2K mishaps. Computer errors may cause the shut-down of vital systems in communication and transportation, in addition to critical infrastructure systems such as power, water, banking, and telecommunications networks. For CVM-regulated products, date coding problems may result in process failures, the production and distribution of adulterated and/or misbranded products, and even product shortages.

The FDA recommends that regulated industries take preventive measures to ensure that they have a Y2K effort in place including:

- Completion of any renovation in sufficient time to ensure a period of monitoring and problem resolution prior to when Y2K problems are expected to occur.
- For mission critical systems, review by an independent contractor/auditor to verify the Y2K compliance status of the systems. (For computerized systems regulated by the FDA, assure all changes have been validated and are in compliance with applicable GMPs).
- Development of contingency plans to ensure business processes will continue unabated regardless of impact of Y2K.

FDA intends to raise the awareness of regulated industries to the potential Y2K problems during routine field inspection activities.

July 1999

It is impossible to predict the extent of the Y2K impact on CVM's customers, but steps have been taken to ensure that CVM's internal computer systems are Y2K-ready.

The steps taken at CVM began with determination of the Y2K compliance status of our inventory of hardware, system software, and application software. Remedial actions have been taken for identified problems, such as upgrading the BIOS of affected desktop computers and LAN servers, applying software service patches, and upgrading to the Y2K compliant version of system software. Compliance strategy has also taken the form of installing newer, compliant versions of desktop operating systems and office automation software. Another strategy has involved the planned re-development of mission-critical database systems by conversion to applications for the LAN environment with the stipulation of Y2K compliance. In these cases, the database applications were subjected to and passed independent verification of Y2K compliance following a prescribed testing process. Finally, CVM is preparing business process continuity contingency plans for major activities in the event of unanticipated power outages from Y2K-related problems.

The Center for Veterinary Medicine (CVM) has identified two major areas that may be vulnerable to potential Y2K computer problems. Those areas are:

1. Sole source suppliers of significant ingredients or finished products.
2. Supplies, especially bulk drug substances, from foreign sources.

CVM has appointed a Y2K Working Group to identify possible problems and to develop a Y2K Rapid Response Plan. The Group has mapped out precautionary steps to assure adequate communication in the event of emergency conditions. Teams have been formed to handle both anticipated and unanticipated issues resulting from Y2K computer problems. In addition, the Center has established contacts with other units of FDA, other Federal agencies, State counterparts, industry trade associations, and consumer groups.

To provide industries with information and guidance on Y2K issues, FDA has been alerting them in direct correspondence, speeches, public appearances, meetings, workshops, and guidance documents. In order to avert problems before they become public health or regulatory issues, FDA and CVM will continue to work with regulated industries to disseminate and exchange information related to Y2K issues.

For more information regarding Y2K, visit the FDA Internet Home Page at <http://www.fda.gov>. For specific Y2K concerns related to animal health, you may contact CVM at 301-594-1736.

Y2K Compatibility – A Feed Industry Checklist

This checklist is for your internal use only.

1. Is your plant's date-sensitive computer software Y2K compliant*?

Software System	Y2K Compliant	Check-Tested	Contingency or Manual Workaround Plan
Scales/Metering Devices			
▶ Truck Scales	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
▶ Ingredient Scales			
• Micro Ingredients	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
• Macro Ingredients	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
• Drug Scales	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
• Bagging Scales	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
▶ Liquid Meters	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
▶ Bulk Bin Scales	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
▶ Batch/Hopper Scales	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
▶ Bagging Scales	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
▶ Grain Inspection Devices			
• Moisture Meters	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
• Infrared Protein Analyzers	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
• _____	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Feed Manufacturing Processes			
▶ Boiler and Air Compressor Controls	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
▶ Feed Formulations/Analysis	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
▶ Automated Systems	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
• Receiving	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
• Grinding	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
• Pelleting	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
• Bagging	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
• Bulk Load-Out	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
▶ Batching System	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
• Cleanout Procedures <i>(sequencing, flushing, etc.)</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
• Inventory Report	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
• Feed Production Records	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
• Drug Inventory Records	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
• Pellet Mill Report	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Label and Records			
▶ Automated Date Coding Equipment	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
▶ Printed Feed Labels	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
▶ Bag Date Coding Shipment	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
▶ Invoices/Distribution Records <i>(for recalls)</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
▶ Automated Date Coding Equipment	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

Quality Control Lab (assays, etc.)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Maintenance/Support Software	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Utility Monitoring Devices	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Alarm and Sprinkler Controls	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

2. Have you solicited and obtained letters from your major suppliers and vendors on whether their plants/operations are Y2K compatible?

[Note: As you survey suppliers and vendors on the Y2K status of their products or operations, it may be valuable to ask for written verification of their status. Request a brief explanation of the processes and steps that they are using to complete their Y2K compatibility efforts. This information will provide valuable documentation as you complete your own Y2K readiness.]

FEED INGREDIENT SUPPLIERS
(Grains, vitamins, premixes, protein, fats, etc.)

Supplier Name	Inquiry Sent	Response Received	On-Site Visit
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

ANIMAL DRUG SUPPLIERS

Supplier Name	Inquiry Sent	Response Received	On-Site Visit
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

OTHER SUPPLIERS

Supplier Name	Inquiry Sent	Response Received	On-Site Visit
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

UTILITIES
(Electrical, Gas, Telephone, etc.)

Supplier Name	Inquiry Sent	Response Received
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

For Further Information: Contact the Y2K Specialist at FDA's Center for Veterinary Medicine at 301-594-1736

Y2K Compatibility – A Checklist
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Do not return to the Center for Veterinary Medicine

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|---|------------|
| 1. Have you taken all necessary steps to assure that the information technology and automated systems, e.g., manufacturing, quality control, distribution systems, used in the facilities responsible for the safe and effective production and distribution of all of your products that will be distributed in the United States are Y2K compliant? | □ Yes □ No |
| 2. Do you have foreign suppliers of materials, e.g., raw materials, equipment, used in the manufacture and/or distribution of your product? | □ Yes □ No |
| 2a. Have you asked these foreign suppliers of their Y2K readiness? | □ Yes □ No |
| 3. Do you have contingency plans, i.e., a plan to deal with potential problems such as problems in obtaining raw materials or in manufacturing, packaging, labeling, or distributing the finished product? | □ Yes □ No |
| 3a. Where appropriate, have the components of the contingency plans been tested? | □ Yes □ No |
| 3b. Do the contingency plans address potential problems with your key business partners (suppliers, vendors, distributors & others)? | □ Yes □ No |
| 3c. Do your contingency plans address potential problems with foreign suppliers? | □ Yes □ No |
| 4. Do you have an Internet site that provides information on the Y2K readiness of your company? | □ Yes □ No |
| 5. Do you have a telephone number or other means to handle inquiries from your customers on your Y2K status? | □ Yes □ No |
| 6. Is your date-sensitive computer software Y2K compliant? | □ Yes □ No |
| 7. Have you asked utilities, e.g., electrical, gas, telephone companies, of their Y2K readiness? | □ Yes □ No |

For Further Information: Contact the Y2K Specialist at FDA's Center for Veterinary Medicine (301-594-1736)
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